

## **Senate Bill No. 1623**

### **CHAPTER 337**

An act to amend Section 100425 of, to add Sections 100701, 100702, and 100703 to, to repeal Sections 100710, 100715, 100720, 100730, 100735, 100740, 100745, 100750, 100755, 100760, 100765, and 100770 of, and to repeal and add Section 100700 of, the Health and Safety Code, relating to laboratories.

[Approved by Governor August 27, 2004. Filed with  
Secretary of State August 30, 2004.]

#### **LEGISLATIVE COUNSEL'S DIGEST**

**SB 1623, Johnson. Laboratories: licensing and accreditation.**

Existing law requires the State Department of Health Services to adopt and publish regulations to be used in approving and governing the operation of laboratories engaging in the performance of tests by or for law enforcement of blood, urine, tissue, or breath samples for the purposes of determining the concentration of ethyl alcohol in the blood of persons involved in traffic accidents or in traffic violations, including the qualifications of the employees who perform the tests, that the department determines are reasonably necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests.

Existing law requires each laboratory in the state that performs those tests to be licensed by the Director of Health Services. Existing law requires the department to periodically inspect every approved and licensed laboratory. If the director orders the suspension or revocation of a laboratory's license, the licensee is required to surrender the license to the director upon the effective date of that order. Existing law authorizes the director, after suspension of the license, to reinstate the license under prescribed conditions.

This bill would repeal all of the above provisions. The bill would instead require laboratories engaging in the performance of forensic alcohol analysis tests by or for law enforcement agencies on blood, urine, tissue, or breath for the purposes of determining the concentration of ethyl alcohol in persons involved in traffic accidents or in traffic violations to comply with various existing department regulations regarding inspection of laboratories, collection and handling of samples, methods of analysis, and laboratory records. The bill would prohibit the department from requiring laboratories to be licensed. The bill would require each laboratory to ensure that breath alcohol instruments and

calibrating devices used in testing are listed in the conforming products list in the Federal Register by the National Highway Traffic Safety Administration of the United States Department of Transportation and would require all laboratories to follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board guidelines for proficiency testing, and to meet other proficiency test requirements.

The bill would require the department, on or before July 1, 2005, to establish a review committee that would be required to meet at least once in each 5-year period thereafter, or within 60 days of receipt of a request by the department or a member of the review committee, to evaluate and determine revisions to relevant department regulations. The bill would require the review committee to submit a summary of those revisions to the California Health and Human Services Agency. The bill would authorize the agency to disapprove one or more of the revisions within 90 days of receiving them. The bill would require the department to adopt regulations to incorporate the revisions determined by the review committee, except for those revisions that the agency disapproves.

The bill would make additional conforming changes to existing law.

*The people of the State of California do enact as follows:*

SECTION 1. Section 100425 of the Health and Safety Code is amended to read:

100425. (a) The fees or charges for the issuance or renewal of any permit, license, registration, or document pursuant to Sections 1639.5, 1676, 1677, 2202, 2805, 11887, 100860, 106700, 106890, 106925, 107080, 107090, 107095, 107160, 110210, 110470, 111130, 111140, 111630, 112405, 112510, 112750, 112755, 113060, 113065, 113845, 114056, 114065, paragraph (2), of subdivision (c) of Section 114090, 114140, subdivision (b) of Section 114290, 114367, 115035, 115065, 115080, 116205, 117923, 117995, 118045, 118210, and 118245 shall be adjusted annually by the percentage change printed in the Budget Act for those items appropriating funds to the state department. After the first annual adjustment of fees or charges pursuant to this section, the fees or charges subject to subsequent adjustment shall be the fees or charges for the prior calendar year. The percentage change shall be determined by the Department of Finance, and shall include at least the total percentage change in salaries and operating expenses of the state department. However, the total increase in amounts collected under this section shall not exceed the total increased cost of the program or service provided.

(b) The state department shall publish annually a list of the actual numerical fee charges for each permit, license, certification, or registration governed by this section. This adjustment of fees and



publication of the fee list shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 2. Section 100700 of the Health and Safety Code is repealed.

SEC. 3. Section 100700 is added to the Health and Safety Code, to read:

100700. (a) Laboratories engaged in the performance of forensic alcohol analysis tests by or for law enforcement agencies on blood, urine, tissue, or breath for the purposes of determining the concentration of ethyl alcohol in persons involved in traffic accidents or in traffic violations shall comply with Group 8 (commencing with Section 1215) of Subchapter 1 of Chapter 2 of Division 1 of Title 17 of the California Code of Regulations, as they exist on December 31, 2004, until the time when those regulations are revised pursuant to Section 100703.

(b) Notwithstanding subdivision (a), the department shall not require laboratories to be licensed.

SEC. 4. Section 100701 is added to the Health and Safety Code, to read:

100701. All laboratories that are subject to the requirements of Section 100700 shall ensure that breath alcohol instruments and calibrating devices used in testing are listed in the conforming products list in the Federal Register by the National Highway Traffic Safety Administration of the United States Department of Transportation.

SEC. 5. Section 100702 is added to the Health and Safety Code, to read:

100702. (a) All laboratories that are subject to the requirements of Section 100700 shall follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing. The required proficiency test must be obtained from any ASCLD/LAB approved test provider.

(b) Each laboratory shall participate annually in an external proficiency test for alcohol analysis.

(c) Each examiner shall successfully complete at least one proficiency test annually.

(d) Each laboratory shall have a procedure in writing that describes a review of proficiency test results, and, if applicable, the corrective action taken when proficiency test results are inconsistent with expected test results.

SEC. 6. Section 100703 is added to the Health and Safety Code, to read:

100703. (a) On or before July 1, 2005, the department shall establish a review committee.

(b) The review committee shall have eight members, including one person representing each of the following:

- (1) Prosecuting attorneys.
- (2) Law enforcement agencies.
- (3) Defense attorneys.
- (4) Coroners, pathologists, or medical examiners.
- (5) Criminalists.
- (6) Toxicologists.
- (7) Crime laboratory directors.
- (8) The State Department of Health Services.

(c) The review committee shall meet at least once in each five-year period after its initial meeting, or within 60 days of receipt of a request by the department or a member of the review committee.

(d) The review committee shall evaluate Group 8 (commencing with Section 1215) of Subchapter 1 of Chapter 2 of Division 1 of Title 17 of the California Code of Regulations and determine revisions that will limit those regulations to those that the review committee determines are reasonably necessary to ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws. The review committee shall submit a summary of revisions to the California Health and Human Services Agency.

(e) Within 90 days of receiving the review committee's revisions, the California Health and Human Services Agency may disapprove of one or more of the revisions.

(f) (1) Except as provided in paragraph (2), the department shall adopt regulations pursuant to this section that shall incorporate the review committee's revisions. Nothing in this section shall be construed as exempting the regulations from the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(2) The department shall not adopt regulations to incorporate any review committee revisions that were disapproved under subdivision (e).

SEC. 7. Section 100710 of the Health and Safety Code is repealed.

SEC. 8. Section 100715 of the Health and Safety Code is repealed.

SEC. 9. Section 100720 of the Health and Safety Code is repealed.

SEC. 10. Section 100730 of the Health and Safety Code is repealed.

SEC. 11. Section 100735 of the Health and Safety Code is repealed.

SEC. 12. Section 100740 of the Health and Safety Code is repealed.

SEC. 13. Section 100745 of the Health and Safety Code is repealed.

SEC. 14. Section 100750 of the Health and Safety Code is repealed.

SEC. 15. Section 100755 of the Health and Safety Code is repealed.



- SEC. 16. Section 100760 of the Health and Safety Code is repealed.
- SEC. 17. Section 100765 of the Health and Safety Code is repealed.
- SEC. 18. Section 100770 of the Health and Safety Code is repealed.

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